STATUTORY INSTRUMENTS.

S.I. No. 572 of 2012

IRISH MEDICINES BOARD (FEES) REGULATIONS 2012

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I, James Reilly, Minister for Health, in exercise of the powers conferred on me by sections 13 and 32 (as amended by sections 15 and 16 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006)) of the Irish Medicines Board Act 1995 (No. 29 of 1995), hereby make the following Regulations:

1. These Regulations may be cited as the Irish Medicines Board (Fees) Regulations 2012.

2. (1) In these Regulations—

"Act" means the Irish Medicines Board Act 1995 (No. 29 of 1995), as amended by s. 197 of the Finance Act 1999 (No. 2 of 1999), Regulation 3 of the European Communities (In Vitro Diagnostic Medical Devices) Regulations 2001 (S.I. No. 304 of 2001), Regulation 2 of the European Communities (Medical Devices) (Amendment) Regulations 2001 (S.I. No. 444 of 2001), Regulation 3 of the European Communities (Medical Devices) (Amendment) Regulations 2002 (S.I. No. 576 of 2002), the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006) and by the European Communities (Amendment of the Medicines Board Act 1995) Regulations 2007 (S.I. No. 542 of 2007);

"Board" means the Irish Medicines Board established by section 3 of the Act;

"certificate of free sale" means a certificate of free sale issued under section 4(1)(*k*)(ii) of the Act;

"certificate of registration" means a certificate of registration granted pursuant to the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007);

"certificate of traditional-use registration" means a certificate of traditional-use registration granted pursuant to the Medicinal Products (Control of Placing on the Market) Regulations 2007 in respect of a traditional herbal medicinal product;

"certification of documents" means the certification, under section 4(1)(*k*)(ii) of the Act, of documents not being certificates of free sale or export certificates;

"complex dossier" refers to an application accompanied by a full dossier in accordance with Directive 2001/83/EC;

"decentralised procedure" means the decentralised procedure for human medicinal products provided for in Directive 2001/83/EC;

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 1*st January*, 2013.

"Directive 2001/83/EC" means Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001[1] on the Community code relating to medicinal products for human use, as amended by Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003[2], Commission Directive 2003/63/EC of 25 June 2003[3], Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004[4], Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004[5], Regulation (EC) No. 1901/2006 of the European Parliament and of the Council of 12 December 2006[6], Regulation (EC) No. 1394/2007 of the European Parliament and of the Council of 13 November 2007[7], Directive 2008/29/EC of the European Parliament and of the Council of 11 March 2008[8], Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009[9], Commission Directive 2009/120/EC of 14 September 2009[10], Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010[11], Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011[12] and Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012[13].

"export certificate" means a certificate issued under section 4(1)(*k*)(ii) of the Act;

"homeopathic medicinal product" has the meaning assigned to it by the Medicinal Products (Control of Placing on the Market) Regulations 2007;

"manufacturer's authorisation" means an authorisation granted pursuant to the Medicinal Products (Control of Manufacture) Regulations 2007 (S.I. No. 539 of 2007);

"marketing authorisation" means an authorisation granted pursuant to the Medicinal Products (Control of Placing on the Market) Regulations 2007;

"mutual recognition procedure" means the mutual recognition procedure for human medicinal products provided for in Directive 2001/83/EC;

"national rules scheme" means the national rules governing the granting of marketing authorisation in respect of homeopathic medicinal products, as provided in Regulation 11 of the Medicinal Products (Control of Placing on the Market) Regulations 2007;

[1]OJ No. L 311, 28.11.2001, p. 67.
[2]OJ No. L 33, 8.2.2003, p. 30.
[3]OJ No. L 159, 27.6.2003, p. 46.
[4]OJ No. L 136, 30.4.2004, p. 85.
[5]OJ No. L 136, 30.4.2004, p. 34.
[6]OJ No. L 378, 27.12.2006, p. 1.
[7]OJ No. L 324, 10.12.2007, p. 121.
[8]OJ No. L 81, 20.3.2008, p. 51.
[9]OJ No. L 168, 30.6.2009, p. 33.
[10]OJ No. L 242, 15.9.2009, p. 3.
[11]OJ No. L 348, 31.12.2010, p. 74.
[12]OJ No. L 174, 1.7.2011, p. 74.
[13]OJ No. L 299, 27.10.2012, p. 1.

"parallel import licence" has the meaning assigned to it by the Medicinal Products (Control of Placing on the Market) Regulations 2007;

"reduced dossier — complex" refers to an application for a generic medicinal product accompanied by a reduced dossier but containing additional data in circumstances required by Directive 2001/83/EC;

"reduced dossier — standard" refers to an application for a generic medicinal product accompanied by a reduced dossier in accordance with Directive 2001/83/EC;

"service item" means an application for a medicinal product designated by the Board as qualifying for a reduced application fee on the basis that the product has limited but important uses for which no alternative authorised product exists;

"subsequent extension applications" means applications in relation to additional pharmaceutical forms and strengths of a medicinal product, made subsequent to the first application in relation to that product;

"switching applications" means applications for a change in the classification of medicinal products under Title VI of Directive 2001/83/EC;

"traditional herbal medicinal product" has the meaning assigned to it by the Medicinal Products (Control of Placing on the Market) Regulations 2007;

"type IB variation" and "type II standard variation" shall be classified by the Board in accordance with Commission Regulation (EC) No. 1234/2008 of 24 November 2008[14], as amended by Commission Regulation (EU) No 712/2012 of 3 August 2012[15];

"wholesaler's authorisation" means an authorisation granted pursuant to the Medicinal Products (Control of Wholesale Distribution) Regulations 2007;

(2) In these Regulations, unless otherwise indicated—

(*a*) any reference to a Regulation is a reference to a Regulation of these Regulations, and

(*b*) any reference to the Schedule is a reference to the Schedule to these Regulations.

3. Subject to Regulation 4, there shall be paid to the Board in respect of each and every matter set out in column 1 of the Schedule the fee as set out in column 2 of the Schedule.

4. The Board may, in circumstances where it considers it appropriate to do so, waive, remit or refund, either in whole or in part, any fee that would otherwise be payable to it under Regulation 3.

[14]OJ No. L 334, 12.12.2008, p. 7.
[15]OJ No. L 209, 4.8.2012, p. 4.

5. The Irish Medicines Board (Fees) Regulations 2011 (S.I. No. 684 of 2011) are hereby revoked.

SCHEDULE

COLUMN 1	**COLUMN 2**
Fees for national applications for marketing authorisations	€
Complex dossier	
National application	15,211
Each additional form (same time)	5,090
Each additional strength (same time)	656
Additional drug master file submitted	3,251
Reduced dossier — complex	
National application	11,329
Each additional form (same time)	5,090
Each additional strength (same time)	656
Additional drug master file submitted	3,251
Reduced dossier — standard	
National application	7,658
Each additional form (same time)	5,090
Each additional strength (same time)	656
Additional drug master file submitted	3,251
Subsequent extension applications	
First additional form	7,658
Each additional form (same time)	5,090
First additional strength (existing form)	2,756
Each additional strength (same time)	656
Additional drug master file submitted	3,251
Fees for applications for marketing authorisations using mutual recognition procedure and decentralised procedure	
Complex dossier	
Mutual recognition incoming	10,647
Each additional form (same time)	3,660
Each additional strength (same time)	656
Outgoing mutual recognition supplement	10,962
Decentralised incoming	15,211
Decentralised outgoing	40,000
Each additional form (same time)	5,090
Each additional strength (same time)	656
Reduced dossier — complex	
Mutual recognition incoming	8,077
Each additional form (same time)	3,251
Each additional strength (same time)	656
Outgoing mutual recognition supplement	10,962
Decentralised incoming	11,329

Decentralised outgoing	30,000
Each additional form (same time)	5,090
Each additional strength (same time)	656
Reduced dossier — standard	
Mutual recognition incoming	5,350
Each additional form (same time)	2,859
Each additional strength (same time)	656
Outgoing mutual recognition supplement	7,126
Decentralised incoming	7,658
Decentralised outgoing	20,000
Each additional form (same time)	5,090
Each additional strength (same time)	656
Subsequent extension applications	
Mutual recognition incoming (first additional form)	5,350
Mutual recognition incoming (first additional strength)	1,929
Mutual recognition incoming (subsequent additional strength)	656
Outgoing mutual recognition/decentralised supplement (additional form)	2,859
Outgoing mutual recognition/decentralised supplement (additional strength)	656
Decentralised incoming (first additional form)	7,658
Decentralised outgoing (first additional form)	20,000
Each additional form (same time)	5,090
First additional strength (existing form)	2,756
Each additional strength (same time)	656
Switching applications	
Switching applications	5,000

Fees for parallel import licences

Application fee — per country at the same time or by variation	1,662
Each additional strength per country	495
Each additional form per country	495
Parallel imports of dual pack registrations	831
Registration of parallel imports — each additional strength or form	495
Parallel imports where the originator is not on the Irish market	5,000
Change of ownership per product range	525

Fees for variations to national marketing authorisations

Type IB variation	468
Type IB variation — reduced rate	234

Type II complex variation	2,601
Type II standard variation	506
Type II standard variation — reduced rate	253
Notifications under Article 61(3) of Directive 2001/83/ EC	250
Notifications under Article 61(3) of Directive 2001/83/EC — reduced rate	125
Multiple variations capped fee (per product range)	5,200
Multiple variations capped fee (per product)	3,400
Worksharing capped fee	5,200
Introduction of standard statements from European institutions	
1 to 5 authorisations	1,500
6 to 10 authorisations	3,000
11 to 20 authorisations	6,000
21 to 40 authorisations	12,000
41 to 100 authorisations	20,000
101 authorisations and above	30,000

Fees for variations to marketing authorisations under mutual recognition procedure and decentralised procedure

Type IB variation outgoing mutual recognition / decentralised supplement	345
Type IB variation — mutual recognition incoming	338
Type IB variation — mutual recognition incoming — reduced rate	174
Type II complex variation — outgoing mutual recognition / decentralised Supplement	525
Type II complex variation — mutual recognition incoming	1,797
Type II standard variation — mutual recognition incoming	338
Type II standard variation — mutual recognition incoming — reduced rate	174
Type II standard variation — outgoing mutual recognition / decentralised Supplement	338
Notifications made under Article 61(3) of Directive 2001/83/EC	250
Notifications made under Article 61(3) of Directive 2001/83/EC — reduced rate	125

Fees for the granting of a marketing authorisation on transfer to another company

Change of ownership — related company — 1st marketing authorisation within a range	900
Change of ownership — related company — additional marketing authorisations within a range	321

Change of ownership — non-related company — 1st marketing authorisation within a range	1,316
Change of ownership — non-related company — additional marketing authorisations within a range	321

Other fees relating to the granting of marketing authorisations

Service item	612

Fees for applications for wholesaler's authorisations

Application fee	555
Variation to authorisation — minor site technical	400
Variation to authorisations — administrative	219
Variation to authorisation — technical	603

Fees for applications for manufacturer's authorisations

Application fee	1,853
Variation to authorisation — administrative	274
Variation to authorisation — technical	768

Fees for the granting of a manufacturer's authorisation or a wholesaler's authorisation on transfer to another company

Manufacture — related companies	1,107
Manufacture — unrelated companies	1,853
Wholesale — related companies	365
Wholesale — unrelated companies	555

Fees for applications in relation to medical devices and cosmetic products

Certificates of free sale — standard (4 certs per request)	147
Certificates of free sale — fast track (4 certs per request)	277
Duplicate certificates of free sale — each (available at time of initial request)	23

Fees for applications in relation to homeopathic medicinal products

New national / decentralised registration standard charge — single stock	678
New national / decentralised registration standard charge — 2 or more stocks	1,016

New application — national rules scheme standard fee — single stock	1,016
New application — national rules Scheme standard fee — 2 or more stocks	1,500
Mutual recognition incoming application standard fee — single stock	452
Mutual recognition incoming application standard fee — 2 or more stocks	678
Outgoing mutual recognition / decentralised supplement	564
National variation — registration and national rules scheme	339
National variation — reduced rate — registrations and national rules scheme	170
Mutual recognition incoming variation	226
Mutual recognition incoming variation — reduced rate	113
Variation — outgoing mutual recognition / decentralised supplement	170

Fees applications in relation to traditional herbal medicinal products

National applications for certificates of traditional-use registration	
National application	4,888
National application where there is a monograph	3,000
Each additional form (same time)	4,072
Each additional strength (same time)	525
Additional drug master file submitted	3,251
Extension applications	
First additional form	4,888
Each additional form at the same time	4,072
First additional strength	2,205
Each additional strength (same time)	525

Applications for certificates of traditional-use registration under mutual recognition procedure and decentralised procedure	
Mutual recognition incoming	3,418
Mutual recognition incoming — each additional form (same time)	2,287
Mutual recognition incoming — each additional strength (same time)	525
Outgoing mutual recognition / decentralised supplement	4,445
Decentralised outgoing/incoming	4,888
Each additional form (same time)	4,072
Each additional strength (same time)	525

Fees for export certificates and certification of documents

Standard	147
Fast track	277

Annual maintenance fees

Marketing authorisations and registrations	
First 10 marketing authorisations	650
Additional marketing authorisations	812
Dormant marketing authorisations	420
Parallel import registration	113
Dual pack registration	55
Homeopathic medicinal products	55
Traditional herbal medicinal products	113
Manufacturer's authorisations	
Major site (more than 250 employees)	16,669
Large site (150-250 employees)	11,112
Medium site (50-149 employees)	7,409
Small site (less than 50 employees)	3,703
Wholesaler's authorisations	
Large full line	2,771
Medium full line / short line	1,576
Small short line	600
Minor site	400
Procurement only	350

Inspection fees

Per day (per member of the inspection team)	1,489
Part of day (per hour, per member of the inspection team)	213

Enforcement fees

Manufacturers	
Major site (more than 250 employees)	2,400
Large site (150-250 employees)	1,800
Medium site (50-149 employees)	600
Small site (less than 50 employees)	200
Wholesalers	
Large full line	600
Medium full line and short line	200
Marketing authorisation / parallel import licence holders	
> 50 marketing authorisations / parallel import licences	3,150
31-50 marketing authorisations / parallel import licences	1,000

16-30 marketing authorisations / parallel import licences	600
6-15 marketing authorisations / parallel import licences	200

(Note: Companies classed as both manufacturer and wholesaler are charged the higher of the two applicable charges. Marketing authorisation holders pay the marketing authorisation holder fee in addition to any manufacturer / wholesaler fee.)

L.S.

GIVEN under my Official Seal,
21 December 2012.

JAMES REILLY,
Minister for Health.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal instrument.)

The purpose of these Regulations is to provide for the revision of fees payable to the Irish Medicines Board pursuant to Section 13 of the Irish Medicines Board Act 1995.

These Regulations revoke the Irish Medicines Board (Fees) Regulations 2011 (S.I. No. 684 of 2011).

Le ceannach ó
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